



PATENT
Customer No. 22,852
Attorney Docket No. 08702.0128-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
WOLFMAN et al.)	Group Art Unit: Not Yet Assigned
)	
Application No.: 10/662,438)	Examiner: Not Yet Assigned
)	
Filed: September 16, 2003)	
)	
For: METALLOPROTEASE ACTIVATION OF)	
MYOSTATIN, AND METHODS OF)	
MODULATING MYOSTATIN ACTIVITY)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 25, 2007

By: Mary K. Ferguson
Mary K. Ferguson
Reg. No. 51,675

INFORMATION DISCLOSURE CITATION

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U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	Publication No. 2003-0104406 (U.S. Appln. No. 10/071,499)	Published June 5, 2003	Wolfman et al.	435	6	February 8, 2002
	5,994,618	11/30/1999	Lee et al.	800	18	February 5, 1997

FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No


OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	Blader et al., "Cleavage of the BMP-4 Antagonist Chordin by Zebrafish Tolloid", <i>Science</i> 278:1937-1940 (1997)
✓	Bogdanovich et al., "Functional Improvement of Dystrophic Muscle by Myostatin Blockade", <i>Nature</i> 420:418-421 (2002)
✓	D'Angelo et al., "Authentic Matrix Vesicles Contain Active Metalloproteases (MMP)", <i>J. Biol. Chem.</i> 276:11347-11353 (2001)
✓	Donoghue et al., "Rostrocaudal Gradient of Transgene Expression in Adult Skeletal Muscle", <i>PNAS</i> 88:5847-5851 (1991)
✓	Gonzalez-Cadavid et al., "Organization of the Human Myostatin Gene and Expression in Healthy Men and HIV-Infected Men With Muscle Wasting", <i>PNAS</i> 95:14938-14943 (1998)
✓	Hill et al., "The Myostatin Propeptide and the Follistatin-Related Gene are Inhibitory Binding Proteins of Myostatin in Normal Serum", <i>J. Biol. Chem.</i> 277:40735-40741 (2002)
✓	Hill et al., "Regulation of Myostatin <i>in Vivo</i> by Growth and Differentiation Factor-Associated Serum Protein-1: A Novel Protein with Protease Inhibitor and Follistatin Domains", <i>Mol. Endocrin.</i> 17:1144-1154 (2003)
✓	Kessler et al., "Bone Morphogenetic Protein-1: The Type I Procollagen C-Proteinase", <i>Science</i> 271:360-362 (1996)
✓	Lee et al., "Regulation of Myostatin Activity and Muscle Growth", <i>PNAS</i> , 98:9306-9311 (2001)
✓	Lee et al., "Analysis of Site-Directed Mutations in Human Pro- α 2(I) Collagen Which Block Cleavage by the C-Proteinase", <i>J. Biol. Chem.</i> 265:21992-21996 (1990)

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✓	Li et al., "The C-Proteinase that Processes Procollagens to Fibrillar Collagens is Identical to the Protein Previously Identified as Bone Morphogenic Protein-1", <i>PNAS</i> 93:5127-5130 (1996)
✓	Lyons et al., "Proteolytic Activation of Latent Transforming Growth Factor- β from Fibroblast-Conditioned Medium", <i>J. Cell Biol.</i> 106:1659-1665 (1988)
✓	Maeda et al., "Activation of Latent Transforming Growth Factor β 1 by Stromelysin 1 in Extracts of Growth Plate Chondrocyte-Derived Matrix Vesicles", <i>J. Bone Min. Res.</i> 16:1281-1290 (2001)
✓	Marques et al., "Production of a DPP Activity Gradient in the Early Drosophila Embryo through the Opposing Actions of the SOG and TLD Proteins", <i>Cell</i> 91:417-426 (1997)
✓	McPherron et al., "Double Muscling in Cattle Due to Mutations in the Myostatin Gene", <i>PNAS</i> 94:12457-12461 (1997)
✓	McPherron et al., "Regulation of Skeletal Muscle Mass in Mice by a New TGF- β Superfamily Member", <i>Nature</i> 387:83-90 (1997)
✓	McPherron et al., "Suppression of Body Fat Accumulation in Myostatin-Deficient Mice", <i>J. Clin. Invest.</i> 109:595-601 (2002)
✓	Pappano et al., "Use of <i>BMP1/Tll1</i> Doubly Homozygous Null Mice and Proteomics to Identify and Validate In Vivo Substrates of Bone Morphogenetic Protein 1/Tolloid-Like Metalloproteinases", <i>Mol. Cell Biol.</i> 23:4428-4438 (2003)
✓	Piccolo et al., "Cleavage of Chordin by Xolloid Metalloprotease Suggests a Role for Proteolytic Processing in the Regulation of Spemann Organizer Activity", <i>Cell</i> 91:407-416 (1997)
✓	Sato et al., "Inhibition of Endothelial Cell Movement by Pericytes and Smooth Muscle Cells: Activation of a Latent Transforming Growth Factor- β 1-Like Molecule by Plasmin During Co-Culture", <i>J. Cell Biol.</i> 109:309-315 (1989)
✓	Scott et al., "Mammalian BMP-1/Tolloid-Related Metalloproteinases, Including Novel Family Member Mammalian Tolloid-Like 2, Have Differential Enzymatic Activities and Distributions of Expression Relevant to Patterning and Skeletogenesis", <i>Devel. Biol.</i> 213:283-300 (1999)
✓	Scott et al., "Bone Morphogenetic Protein-1 Processes Probiglycan", <i>J. Biol. Chem.</i> 275:30504-30511 (2000)
✓	Sternberg et al., "Identification of Upstream and Intragenic Regulatory Elements that Confer Cell-Type-Restricted and Differentiation-Specific Expression on the Muscle Creatine Kinase Gene", <i>Mol. Cell Biol.</i> 8:2896-2909 (1988)
✓	Takahara et al., "Bone Morphogenetic Protein-1 and a Mammalian Tolloid Homologue (mTld) Are Encoded by Alternatively Spliced Transcripts Which Are Differentially Expressed in Some Tissues", <i>J. Biol. Chem.</i> 269:32572-32578 (1994)
✓	Takahara et al., "Characterization of a Novel Gene Product (Mammalian Tolloid-like) with High Sequence Similarity to Mammalian Tolloid/Bone Morphogenetic Protein-1", <i>Genomics</i> 34:157-165 (1996)
✓	Thies et al., "GDF-8 Propeptide Binds to GDF-8 and Antagonizes Biological Activity by Inhibiting GDF-8 Receptor Binding", <i>Growth Factors</i> 18:251-259 (2001)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Uzel et al., "Multiple Bone Morphogenetic Protein 1-Related Mammalian Metalloproteinases Process Pro-Lysyl Oxidase at the Correct Physiological Site and Control Lysyl Oxidase Activation in Mouse Embryo Fibroblast Cultures", <i>J. Biol. Chem.</i> 276:22537-22543 (2001)
	Yu et al., "Cell Surface-Localized Matrix Metalloproteinase-9 Proteolytically Activates TGF- β and Promotes Tumor Invasion and Angiogenesis", <i>Genes Dev.</i> 14:163-176 (2000)
	Wagner et al., "Loss of Myostatin Attenuates Severity of Muscular Dystrophy in <i>mdx</i> Mice", <i>Ann. Neurol.</i> 52:832-836 (2002)
	Whittemore et al., "Inhibition of Myostatin in Adult Mice Increases Skeletal Muscle Mass and Strength", <i>Biochem. Biophys. Res. Comm.</i> 300:965-971 (2003)
	Wozney et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities", <i>Science</i> 242:1528-1534 (1988)
	Zimmers et al., "Induction of Cachexia in Mice by Systemically Administered Myostatin", <i>Science</i> 296:1486-1488 (2002)

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce